510(k) SUMMARY

OCT 13 2006

NAME OF FIRM:
DePuy Orthopaedics Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Establishment Registration No.: 1818910

510(K) CONTACT:
Nancy Friddle
Team Leader, Regulatory Affairs
Tel: (574) 371-4923
Fax: (574) 371-4987

TRADE NAME: DePuy LPS Proximal Tibial Component

COMMON NAME: Proximal Tibial Replacement

CLASSIFICATION: Knee joint femorotibial metal/polymer constrained cemented prosthesis: Class II per 21 CFR §888.3510

DEVICE PRODUCT CODE: KRO

SUBSTANTIALLY EQUIVALENT DEVICES:
DePuy Orthogenesis LPS Proximal Tibial Replacement System (K011810)

DePuy LPS (K033959)

DEVICE DESCRIPTION:

The DePuy LPS Proximal Tibial Component is a modular component that is designed to replace the proximal portion of the tibia. Unlike primary knee systems, the LPS System is used when the amount of bone resection and replacement is extreme (e.g. in oncology cases or endstage revision).

The distal end of the LPS Proximal Tibial Component has a female Morse-type taper that is designed to accept either a DePuy LPS Segment Component or a tibial stem. The proximal/superior surface is designed with a central stem hole to allow it to accept the stem of the LPS tibial plateau/hinge assembly. The top surface has a highly polished mirror finish for smooth articulation with the polyethylene component of the tibial plateau/hinge assembly. The anterior surface has a Porocoat beaded Co-Cr-Mo porous coating.

INDICATIONS FOR USE:

The DePuy LPS is intended for use in replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include:

- malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement;
- revision cases for a failed previous prosthesis requiring extensive resection and replacement;
- severe trauma requiring extensive resection and replacement.

The LPS is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The distal femoral component, the S-ROM Tibial Tray and the non-porous coated straight and bowed stems are intended for cemented use only.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

DePuy believes that this device is substantially equivalent to the Orthogenesis LPS Proximal Tibial Replacement System based on similarities in design and indications and the results of physical testing and analysis compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2006

DePuy Orthopaedics, Inc.
% Ms. Nancy Friddle
Team Leader, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46581

Re: K062301
Trade/Device Name: LPS Proximal Tibial Component
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femortibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: October 5, 2006
Received: October 6, 2006

Dear Mr. Friddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

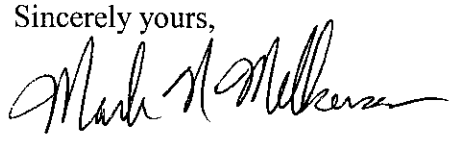
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K062301

Device Name: DePuy LPS Proximal Tibial Component

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062301

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